

Exhibit 7-12

AUDIT CHECK REPORT INSTRUCTIONS/EXPLANATION BY SECTION

NOTE: COMPLETE ONE FORM PER AUDIT CHECK; HOWEVER, PROGRAM DATA MAY COVER NUMEROUS AUDIT CHECKS.

1. Recall Information:
 - a. Recall Number - Enter the recall number assigned by the Center. If more than one number is involved, enter the lead number.
 - b. Recalling Establishment - Provide the name and address of the firm responsible for issuing the recall notification.
 - c. Recalled Codes - Provide the lot, batch, or serial number under recall.
 - d. Product - Provide the name of the product under recall. If numerous products are involved, use generic term, e.g., ice cream, dried fruit, etc.

2. Program Data:

Completion of Section 2 is required only if the credit sheet is to be used for program data reporting. Form FDA 2123 may also be used for reporting audit check data. If time is reported on either a FDA 2123 or another FDA 3177, check the box and do not complete Section 2.

 - a. Accomplishing District - Enter the code for the district conducting the audit check.
 - b. Home District - Enter the code for the home district of the recalling establishment listed in 1b.
 - c. Operation Code for Audit Checks - Operation 17, has been pre-printed.
 - d. Operation Date - Provide the date the audit check was conducted. When multiple checks are reported, use the date of the last audit.
 - e. Central File Number or FEI- Provide the CFN or FEI for the recalling establishment listed in Block 1b.
 - f. PAC Code - Enter appropriate PAC code.
 - g. Employee - Self-explanatory.
 - h. Provide a breakdown of the number of visits and phone audits conducted. Time for each type of check should be listed under the Hours column.

3. Audit Accounts: The form has been designed so that it may be used at the tertiary level of distribution, that is, as far down the distribution chain as consignees of secondary distributors.

4. Consignee Data: "Consignee" is the account at which the check is being conducted. Data requested is self explanatory.

5. Notification Data: Fill in appropriate blocks. Did consignee receive a specific written, verbal, or personal contact providing recall notification; from whom and when was notice received?

6. Action and Status Data: Self-explanatory

7. Sub-Recall Needed: Describe firm's sub-recall procedures in Block 10 or give reason for not conducting sub-recall. If firm has refused to sub-recall properly without justification, include district follow-up in Block 10 or separate memo.
8. Self-explanatory.
9. Self-explanatory.
10. Remarks: Provide all information not covered in 1-9 which aids in the evaluation of recall effectiveness at this consignee.

The Recall Audit Check Report is to be signed by the individual conducting the check as well as the individual endorsing the report to the monitoring district.